UNITED STATES DISTRICT COURT Southern District of New York

In re Pfizer Inc.	
Shareholder Derivative Litigation	No. 09-CV-7822

AFFIDAVIT OF JEFFREY N. GORDON IN SUPPORT OF PLAINTIFFS' MOTION FOR FINAL APPROVAL OF DERIVATIVE ACTION SETTLEMENT

Introduction

- 1. This affidavit provides my opinion and reasoning regarding the Corporate Governance Reforms ("the Reforms") agreed to by the board of directors ("the Board") of Pfizer Inc. ("Pfizer" or "the Company") in connection with the proposed settlement of the above-captioned litigation ("the Litigation"), as reflected in the Settlement Stipulation ("the Proposed Settlement").
- 2. In my opinion, the Reforms embodied in the Proposed Settlement will significantly strengthen Board oversight of Pfizer's compliance with the FDA's drug marketing regime and related compliance mandates and will produce other improvements to internal compliance and accountability. In particular, the new Board committee, the "Regulatory and Compliance Committee" (the "Regulatory Committee") will significantly add to the Board's capacity to oversee Pfizer's compliance process and to the Board's capacity to act should a problem appear. The result will be to reduce the possibility of recurrent wrongful corporate conduct by Pfizer as evidenced by the guilty plea and \$2.3 billion fine in the 2009 settlement of U.S. Government charges. Because of the financial and franchise risks to the Company from further violations of the FDA regulatory regime, these Reforms will thus provide significant value for Pfizer and it shareholders.
- 3. Moreover, Pfizer's creation of a Regulatory and Compliance Committee, as called for in the Proposed Settlement, could well provide a model that other firms with significant

compliance obligation will emulate. As one of the 20 largest firms in the United States (by market capitalization), Pfizer's example is likely to be a powerful one.

4. This affidavit describes the Reforms and provides the basis for my opinion that each Reform will produce benefits for the shareholders of Pfizer, whose interests this Litigation aims to further. I also participated in the formulation of the Reforms and was consulted by Plaintiffs' Counsel during the negotiations that led to the Proposed Settlement. I will briefly describe that process.

Qualifications

- 5. I have been retained in this matter as an expert on corporate law and governance and directors' fiduciary duties.
- 6. As I stated in a preliminary affidavit filed in this matter, ¹ I am the Alfred W. Bressler Professor of Law at Columbia Law School, Co-Director of the Columbia University Center for Law and Economic Studies, and a Fellow of the European Corporate Governance Institute. I have been a law professor for more than 25 years, starting at NYU Law School in 1982 and moving to Columbia in 1988. In the fall of 2002, I was the Bruce W. Nichols Visiting Professor of Law at Harvard Law School. Most of my teaching and scholarship have been in the corporate and securities area, broadly defined. I have become a specialist in corporate law (including the fiduciary duties of boards and directors), corporate governance, corporate finance, and mergers and acquisitions. I have taught Corporations or Advanced Corporate Law: Mergers and Acquisitions on a yearly basis throughout my career. Recently, I have regularly taught courses that focus on various aspects of corporate governance. I also regularly participate in continuing legal education panels on corporate law and governance and mergers and acquisitions topics. Further professional background is provided by my c.v., attached as Exhibit 1 hereto.
- 7. Of particular relevance to the opinions I express in this affidavit, I have written extensively on the board's role in corporate governance. A recent article on the role of boards and independent directors in corporate governance, *The Rise of Independent Directors in the United States: 1950-2005*, 59 Stan. L. Rev. 1465 (2007), was selected by a vote of business law academics as one of the 10 best articles on business law published in the United States during 2007 and was awarded the European Corporate Governance Institute's Egon Zehnder International Prize for the best working paper in 2007 on company boards and their role in corporate governance. Another much-discussed article directly addressed the responsibility of the Enron board in that company's collapse, *Governance Failures of the Enron Board and the New Information Order of Sarbanes-Oxley*, 35 U. Conn. L. Rev. 1125 (2003) (symposium issue).

¹ Affidavit of Jeffrey N. Gordon in Support of Plaintiffs' Motion for Preliminary Approval of Derivative Action Settlement (Dec. 1, 2011).

- 8. My article calling for board responsibility in reviewing and approving disclosures relating to executive compensation was cited by the Securities and Exchange Commission ("SEC") in connection with its own similar rule, *Executive Compensation: If There is a Problem, What's the Remedy? The Case for "Compensation Discussion and Analysis,"* 30 J. Corp. Law 675 (2005). An article on the governance role of controlling shareholders, *Controlling Controlling Shareholders*, 152 U. Penn. L. Rev. 785 (2003) (with Ronald J. Gilson), also selected as a "top ten" article, has been cited and relied upon several times by the Delaware Chancery Court. Other articles addressing other corporate law issues have also been cited by the Delaware Chancery Court. I am also a co-author of **The Law and Finance of Corporate Acquisitions**, 3d edition (in preparation) (with Ronald J. Gilson, Bernard S. Black, John C. Coates, Jr., and Charles Whitehead), a leading casebook in the mergers and acquisitions field, which extensively treats the standards of board behavior in business decision-making.
- 9. More recently I have begun to address the governance problems of financial firms, including a recently-released working paper that focuses on the interaction of compensation incentives and corporate governance, *Executive Compensation and Corporate Governance in Financial Firms: The Case for Convertible Equity-Based Pay*, available at http://ssrn.com/abstract=1633906.
- 10. In the course of teaching and scholarship in the corporate law and corporate governance areas, I have become very familiar with the law of Delaware, whose courts are the most important U.S. expositor of corporate law norms, including the fiduciary duties of directors. I regularly use the Delaware corporate statutes and case law in my teaching and scholarship.
- 11. I also participate in the international dialogue about corporate governance and sophisticated business transactions. As indicated in my c.v., I have written a number of articles on international corporate governance standards and have co-edited **Convergence And Persistence In Corporate Governance** (with Mark J. Roe) (2004). My work has been translated into German, French, and Chinese. I am currently working as part of a multinational, interdisciplinary team to study the effect of national takeover laws on the level of cross-border mergers and acquisitions activity. As previously noted, I am a Fellow of the European Corporate Governance Institute, a leading interdisciplinary group of economists and lawyers.
- 12. On a number of occasions I have been retained by agencies of the United States government (namely, the office of the U.S. Attorney for the Southern District of New York, the office of the U.S. Attorney for the Eastern District of New York, the Securities and Exchange Commission, the Board of Governors of the Federal Reserve System and the Internal Revenue Service) to serve as an expert witness in pending criminal or civil litigation, involving various matters of corporate and securities law, including but not limited to various questions of corporate governance, board behavior, controlling shareholder responsibilities, corporate structure, and finance. In all cases where I was called upon to testify or submit an affidavit, and where the court permitted expert testimony, I have been accepted as an expert.

- 13. I have also submitted affidavits as a corporate governance expert in recent settlements of shareholder derivative suits in connection with stock option backdating and proxy statement disclosure issues.
- 14. In preparing this affidavit, I have reviewed the litigation material identified in Exhibit 2 attached hereto.

Process

- 15. I was retained on November 3, 2010 by Bernstein Litowitz Berger & Grossmann LLP, the Plaintiffs' lead counsel, as a corporate governance expert in connection with a possible settlement of the matter herein. I participated in formulating the Corporate Governance Reforms that are reflected in the Proposed Settlement. Based on my review of the record in this Litigation and discussions with counsel regarding the evidence uncovered, I strongly urged the formation of a new Board committee, later designated the Regulatory and Compliance Committee, given specific oversight powers and responsibility for the drug marketing and other compliance areas addressed by this Litigation. Later in this affidavit I explain why I think this is a particularly important element of governance reform.
- Corporate Governance Reforms, with Defendants' counsel. At various stages in the negotiations, Plaintiffs' lead counsel consulted with me regarding Defendants' various positions in response to Plaintiffs' proposals. In this regard, I advised Plaintiffs' lead counsel about elements of the proposals that I thought were critical to a meaningful settlement and resisted changes suggested by Defendants that I regarded as unjustified by the concerns raised by Defendants' counsel. For example, I insisted on an initial term of the new Committee of at least five years, in the belief that a significant time period was necessary for Board oversight of compliance and other regulatory matters to take root in the Pfizer culture. In my opinion, the final agreement embodies the essential elements of the initial proposal; most of the modifications addressed credible business or legal concerns raised by defendants that seemed sound from a shareholder point of view.
- 17. Without meaning to overstate my role in the negotiations, this was not a case in which counsel negotiated a settlement that included corporate governance reforms and then brought in an expert to opine on their value.

Summary of Corporate Governance Reforms

- 18. The Proposed Settlement is aimed specifically at the alleged corporate governance failures of the Pfizer Board. It contains four important substantive corporate governance provisions:
 - i. The creation of a new and independently funded Board committee, the Regulatory and Compliance Committee, with oversight responsibility and authority over a broad range of the Company's compliance duties;
 - ii. The creation of an Ombudsman Program designed as an alternative channel for employees to express work-related concerns, including those related to marketing-practices, with a direct channel to the Regulatory and Compliance Committee;
 - iii. A required Board-level procedure for considering potential perverse compensation incentives for employees marketing Pfizer's drugs; and
 - iv. For instances of significant compliance wrong-doing, a required Board-level procedure for determining whether to obtain compensation clawback for corporate officials involved in the conduct or with direct supervision over those employees engaged in the conduct.
- 19. The Reforms also provide that the Regulatory and Compliance Committee can draw on a dedicated fund created in connection with the Proposed Settlement, \$75 million less attorney's fees and expenses as awarded by the Court, that the Committee can use in fulfilling its responsibilities, including the retention of outside counsel and experts as it deems appropriate.

Reform One: Establishment of a "Regulatory and Compliance Committee" of the Board

- 20. The most important governance innovation of the Proposed Settlement is Pfizer's establishment of a new Board committee, the Regulatory Committee, tasked with bringing focused oversight to compliance and other regulatory issues. In my opinion this Committee is structured so as to significantly reduce the probability that Pfizer will backslide into the compliance-related violations reflected in the 2009 plea agreement and settlement with the Government. This is for two interrelated sets of reasons: First, the Proposed Settlement creates tools and incentives for credible Committee oversight of compliance and regulatory matters. Second, the Committee set-up will foster more robust and independent internal monitoring and thus an extra-Committee check on potential compliance and regulatory violations.
- 21. To expand a bit: The Committee's oversight will be informed by internal and external information streams and will be supported by adequate authority and resources to follow up on red (or yellow) flags. The independent director members will have a strong reputational (and perhaps liability-avoiding) stake in avoiding a major compliance failure on their watch. These elements make oversight credible.

22. The Committee's activity will also strengthen internal monitoring. Internal monitors will know that their reports will reach the Committee unfiltered by senior management screening and will be subject to external review by outside experts as part of the Committee's process. Moreover, the Committee may engage directly with monitoring personnel without senior management participation. These elements – access and accountability to a Board Committee – will buttress the independence of the internal monitoring function.

Scope of the Mission

23. The Committee has broad oversight responsibility with respect to Pfizer's substantive regulatory and compliance obligations. These include not only the FDA's drug marketing requirements, but also a broad range of other regulatory matters: compliance with the Foreign Corrupt Practice Act limits on marketing outside the US; Medicare and Medicaid regulations; and compliance with key drug safety regulations, including those that pertain to drug manufacturing quality control, clinical studies quality control, and required drug safety reporting to the FDA. (Stipulation and Agreement of Settlement, Annex A, ¶ I.)

Structure of the Committee

24. The Committee will consist of a majority of independent directors and must be headed by an independent director who joined the Board after Jan 1, 2007 (that is, after the events complained of in the Government complaint) and who has relevant experience in law, corporate compliance, regulatory or governmental affairs, academia or service on the Board of a healthcare institution or a highly regulated company. At least one Committee member must be a person with significant background in healthcare. (Id., ¶ I.D.) The Committee must prepare an annual review of its activities for inclusion in the Pfizer proxy statement or annual report, signed by the chairperson and all members. (Id., ¶ I.C.) The Committee will have a minimum five year term (Id., ¶ I.) In deciding whether to extend the Committee's term, the Board must obtain a written recommendation from the Committee and report its decision to the shareholders. (Id., ¶ IX.)

Board oversight of compliance

25. The general charge in its charter is for the Committee to engage with two distinct information streams: internally-generated monitoring reports and complaints from external sources, such as federal and state officials, Company employees, and members of the public. On the basis of red or yellow flags in either of these information streams, the Committee can commission investigations by independent counsel and experts and force corrective action.

- 26. These are the information streams (Id., \P I.A.(b)):
- i. Annually, a report from the Chief Compliance Officer or the product attorney for drugs with a high risk of off-label use as well as new drugs, to assure that the marketing of such drugs complies with the FDA-approved label;
- ii. Drug usage reports for signs of off-label use. Suggestive usage levels, including changes in usage levels, will trigger requests for further information and analysis from management;
- iii. FDA warning letters and the Company's responses, and review of reports on implementation of corrective measures;
- iv. Qui Tam suits, including a review of an analysis of the underlying factual allegations;
 - v. Detailed reports on government investigations;
- vi. Annually, a report from the Chief Compliance Officer or the relevant product attorney for three drugs with more than \$500 million in annual sales, on how marketing of the drug complies with Pfizer's internal risk evaluation system, "RAMP";
- vii. At least annually, a report from the Company's internal Compliance Group on on-going compliance investigations;
- viii. At least annually, a report from Internal Audit (a critical element of the Company's internal compliance system) on health care compliance audits run during the year, with special analysis of compliance risks of "unsatisfactory" audits;
- ix. At least annually, a report from senior management (the "Executive Compliance Committee") on key compliance issues and the steps being taken to address them; and
- x. At least annually, a report on retaliation claims, including lawsuits, settlements, and allegations made to compliance officials or the Ombudsman.
- 27. Since some of the problems that were the subject of the Litigation originated with companies acquired by Pfizer, the Regulatory Committee is given specific review and oversight mandates. In particular, after the acquisition the Committee is directed to obtain various reports relating to the newly acquired entity (Id., ¶ I.A.(b)):
 - i. A report by the Compliance and Legal Departments as to compliance, regulatory, or criminal problems and investigations, including Qui Tam actions and pending FDA warning letters; and

- ii. A specific timetable (and progress reports) for training the new employees and integrating the compliance personnel and procedures of the acquired company into Pfizer's system.
- 28. Although these particular information streams and follow-on responsibilities were designed at least in part to address specific oversight problems that Plaintiffs believe became evident in the course of the Litigation, in my opinion they are formulated broadly enough as to provide useful guidance for the on-going compliance mission.
- 29. Such particularized requirements have at least four pro-compliance related effects, each of which should reduce the incidence of serious and unaddressed compliance problems.
- 30. First, the requirements provide impetus for information collection and the drafting of reports by internal compliance and other key Company employees. Since a firm can act only through its agents, such information gathering activity is, in effect, a mechanism for making the "Company" aware of problems, a way to create entity self-knowledge. This itself can have a positive effect on compliance levels, as different internal groups are required to take responsibility for identifying and solving compliance issues.
- 31. Second, the Committee will receive "raw" information from external sources on possible compliance issues, in the form of FDA warning letters, significant Qui Tam actions, and government investigations. Knowledge of such receipt is likely to spur employee efforts to address compliance issues quickly and effectively, so the Committee can evaluate such external markers of compliance alongside the Company responses.
- 32. Third, knowledge of problems or potential problems will call forth independent evaluation by Committee members and, in significant cases, can be expected to produce a Board-level response.
- 33. Fourth, knowledge that Board members will be directly exposed to compliance issues will enhance senior management's sense of accountability and create incentives throughout managerial ranks to respond more vigorously to compliance issues as they arise.

Regulatory Committee Authority to Obtain Additional Information

- 34. The Charter of the Regulatory Committee also gives the Committee significant authority to initiate audits and other investigations on compliance, regulatory, and legal concerns. Thus in performance of its compliance oversight function the Committee is not just a passive recipient of reports produced by others but can catalyze the gathering and dissemination of information relevant to its responsibilities. These report initiation powers take at least four forms (Id., ¶ I.B.):
 - i. The Committee can trigger internal investigations, meaning that the Committee can require management to conduct audits on relevant matters;

- ii. The Committee can trigger external investigations, meaning that it can retain independent outside counsel and other experts to investigate relevant matters;
- iii. The Committee may commission surveys of doctors or the creation of registries to track usage of Pfizer drugs as a way of surfacing potential off-label marketing issues; and
- iv. The Committee is specifically authorized to meet privately with any senior manager or employee.
- 35. In addition, the Committee is directed to commission biannual external reviews of Pfizer's policies for significant healthcare-related compliance, regulatory, and legal issues. (Id., \P I.B.(c))
- 36. In general the Committee's authority to initiate investigations will buttress the Committee's oversight credibility.
- 37. The authority to trigger external investigations has a two-fold effect. First, such investigations may be critical to the Committee's coming to understand a serious compliance or regulatory matter. The Committee's authority may mean sooner uncovering of a significant regulatory or compliance issue and thus lead to quicker resolution.
- 38. Second, the authority may spur internal report producers to supply the Committee with complete, candid reports, since a dissatisfied Committee has other ways to obtain information. Internal reports are subject to third-party verification; the Committee is not a captive of potentially incomplete or self-serving internal reporting. Because internal monitors will be aware that their reports may be externally scrutinized, they will feel pressure for greater accuracy and candor, making the reports more reliable and useful. This in turn will make the Committee more effective.
- 39. Private access to Company employees is also an important source of information. Such access can help break down the potential for conspiracy of silence about embarrassing compliance matters. Knowledge of such Committee access an alternative source of verification will also heighten pressure for reporting candor among internal monitors.

Resources

40. The Proposed Settlement also provides the Committee with a dedicated fund, \$75 million less certain expenses and fees associated with the Litigation. (Stipulation and Agreement of Settlement, ¶ 2(b)) The Proposed Settlement also provides that the Company will provide whatever additional resources are deemed necessary by the Committee. (Id., Annex A, ¶ VII.) The initial fund has a useful structure: after the Committee's initial five year term, unused funds will revert to Pfizer's insurers. This dedicated funding structure thus protects the Committee from the assertion that it is diverting resources that could fund other Pfizer priorities. It

therefore makes more credible the Committee's capacity to engage outside counsel and experts to conduct external investigations, with all the benefits that flow from that, as described above.²

Reputation

- 41. In general, independent directors post a reputational bond with respect to the companies on whose boards they serve. Since monetary liability for breach of duty is remote for independent directors,³ high reputation is valuable in establishing the credibility of the director's undertaking to engage in the necessary monitoring. This is why companies may recruit independent directors of stature and distinction as well as relevant skill sets; investors may believe that director diligence will be positively correlated with the threat of reputational loss. Reputational loss can take a more concrete form than an embarrassing story in the financial press that leads to social reproof; most notably, it can include the loss of current and future board seats.
- 42. The reputational bond becomes greater as responsibility and accountability becomes more narrowly focused. Concentrating responsibility on a board committee comprised of a small group of directors creates a greater reputational threat than diffusing responsibility across the entire board. This is borne out by the empirical literature that examines director turnover following accounting restatements. ⁴ The likelihood of director turnover is greater following a restatement, but is greater still for directors on the audit committee. The likelihood of turnover, especially on the audit committee, increases in the duration and magnitude of the misstated results. Moreover, directors in restating firms particularly audit committee members face greater risk of losing directorships in *other* firms. Presumably this reflects the director's loss of reputation because of an accounting problem that occurred despite his/her purported oversight.
- 43. These general points help explain the value of a Regulatory Committee at Pfizer. First, creation of a Regulatory Committee with focused compliance responsibilities places responsibility for oversight of this critical function on a small group of independent directors. Previously this responsibility belonged to the Audit Committee, but the post-Enron post-SOX focus of the Audit Committee on financial reporting may have diminished investor expectation of close compliance oversight and thus the reputational threat of limited oversight of this area. A Committee tailored for compliance and other regulatory oversight heightens the reputational threat and thus provides much stronger incentives to fulfill the responsibility.

² The importance of resources to the effectiveness of a monitoring committee is emphasized in the empirical literature on audit committee effectiveness. See, e.g., F. Todd DeZoort et al, Audit Committee Effectiveness: A

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Synthesis of the Empirical Audit Committee Literature, 21 J. Accounting Lit. 38, 44-45, 58-62, 67 (2002).
³ See Bernard Black, Brian Cheffins, and Michael Klausner, Outside Director Liability, 58 Stanf. L. Rev. 1055 (2006).

⁴ See Suraj Srinivasan, Consequences of Financial Reporting Failure for Outside Directors: Evidence from Accounting Restatements and Audit Committee Members, 43 J. Accounting Research 291, 331 (2005) ("[F]or severe restatements the likelihood of departure is higher for audit committee members, who have direct responsibility for overseeing the financial reporting process, than for non-audit committee directors.")

- 44. Second, Pfizer's size (one of the 20 largest U.S. firms by market capitalization, a constituent of the Dow-Jones stock market index) assures that a compliance or regulatory blow-up would be a major story in the financial press. Moreover, the loss of a Pfizer board seat would be a damaging reputational blow. Recurrence of a serious compliance problem that led to Government action would particularly increase the likelihood of the loss of a Pfizer board seat for directors who served on the Regulatory Committee. Apart from decisions of the Board (or the Nominating Committee), shareholders could be expected to wield the "withhold vote" tool to seek to unseat responsible directors. This has become a frequent shareholder measure against offending audit committee members (restatements) or compensation committee members (purportedly excessive contracts).⁵
- 45. Moreover, Pfizer directors commonly sit on boards of other public companies, on average two other boards per director. As shown by previously-cited evidence, those seats could well be at risk for directors who sat on a Pfizer Regulatory Committee that failed to detect and avoid a major compliance problem, in light of the Committee's targeted mission and available resources. Thus in creating the Regulatory Committee, the Pfizer settlement creates strong reputational incentives for robust oversight of the compliance and regulatory area.

Why a Regulatory Committee in Addition to an Audit Committee

- 46. The establishment of a Regulatory Committee for a company like Pfizer, which operates in a heavily regulated industry, represents a genuine advance in corporate governance, reflecting an evolving conception of the monitoring board. Simply put, the Audit Committee's oversight of financial reporting is too time-consuming to expect a comparable effort in the compliance area. Plaintiffs claim that the Litigation demonstrated how relatively little attention the Pfizer Audit Committee paid to compliance matters. Apart from this Litigation, for a firm like Pfizer a separate Regulatory Committee is a desirable innovation.
- 47. Beginning with the institution of the audit committee in the 1970s, corporate governance reformers have pressed for discrete board committees that would take responsibility for certain key areas of the board's monitoring of managerial performance. The creation of these committees has coincided with the rise of institutional investors, a class of longterm shareholders in major public firms who see improved governance as a mechanism to improve the value of their portfolios. Such institutions want alternatives to the "Wall Street Rule" of selling out their position (exit) to address particular managerial performance issues. Stock-exchange listed firms now have, at minimum, compensation committees and nominating committees in addition to audit committees.

⁵ See generally Diane Del Guercio et al., Do Boards Pay Attention when Institutional Investors 'Just Vote No'?, 90 J. Fin. Econ. 84 (2008); Jeffrey N. Gordon, Proxy Contests in an Era of Increasing Shareholder Power, 61 Vand. L. Rev. 475, 481-83 (2008).

⁶ Pfizer, Inc., Notice of Annual Meeting of Shareholders and Proxy Statement 25-32 (March 16, 2010) (credentials of director nominees).

⁷ See Jeffrey N. Gordon, The Rise of Independent Directors in the United States, 1950-2005: Of Shareholder Value and Stock Market Prices, 59 Stan. L. Rev. 1465 (2007).

- 48. From the beginning, the audit committee had oversight responsibility for both financial reporting and compliance. Indeed, an early impetus to audit committee formation in the 1970s was to address the "questionable payments" made by US issuers to foreign government officials that led to the Foreign Corrupt Practices Act, a compliance issue.
- 49. The Enron and WorldCom financial reporting and accounting scandals led to a dramatic change in the role of the audit committee, ratcheting up the expectations of sustained audit committee engagement with an issuer's financial reporting process. Most notable, of course, is the enactment of the Sarbanes-Oxley Act in 2002 (SOX). Various sections of SOX require significant new interaction between the audit committee and the public accounting firm that audits the issuer's financial statements. For example, the audit committee now receives reports on "critical accounting policies and practices" and on the auditors' disagreements with management's proposed treatment of financial information. See Securities Exchange Act, § 10A(k). In connection with its audit oversight function, the audit committee will necessarily become involved in the accounting firm's assessment of the issuer's internal controls, a major auditor responsibility under SOX and often a major issue of concern.
- 50. The audit committee is also responsible for overseeing the issuer's relationship with the independent accounting firm, including hiring and setting the fee and determining whether the accounting firm can engage in certain non-audit activity with the firm. See id., §§10A(l), (m). The audit committee also must establish procedures for internal reporting of possible accounting irregularities. As a practical matter, at least one audit committee member must be a "financial expert." See SOX § 407. The Federal Securities Laws also require the audit committee to prepare and sign a report for inclusion in the issuer's annual proxy statement. See Regulation S-K, Item 407(d)(3), 17 CFR § 229.407(d)(3).
- 51. In addition, the New York Stock Exchange Listing Standards establish additional requirements for audit committee membership and function that further focus the audit committee on the financial reporting function. See NYSE Listed Company Manual, ¶ 303A.07. For example, all members of the audit committee must be "financially literate," and at least one must have "accounting or related financial management expertise." The audit committee must have a charter with a minimum set of specified responsibilities. Three of these responsibilities heavily focus on financial reporting; a fourth picks up "compliance with legal and regulatory requirements." The listing standards contemplate that the audit committee will meet quarterly and annually to discuss accounting matters with management and the auditors and must oversee policy on earnings releases as well as financial guidance provided to analysts. Of four text pages in the NYSE listening standards on the audit committee, "compliance" gets decidedly short shrift.
- 52. The charter of the Pfizer Audit Committee reflects the general expectation that an audit committee's main mission is to protect the reliability of the issuer's financial reporting.⁸ The Pfizer charter identifies 16 "Responsibilities." The first four relate to the retention and

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⁸ The Pfizer Audit Committee Charter is posted as Annex 2 to the Company's 2010 Proxy Statement, which is posted on the Pfizer website.

evaluation of Pfizer's independent public accountants, including an annual review of the accounting firm's regulatory track record and an annual review of the continuing "independence" of the accounting firm.

- 53. The second six relate directly to the accounting firm's audit of Pfizer's financial statements and its audit of Pfizer's internal controls. These reviews entail at least quarterly meetings. In particular, the Audit Committee must meet at least quarterly to "review the Company's specific disclosures under 'Management's Discussion and Analysis of Financial Conditions and Results of Operations'" included in quarterly and annual reports. In effect the Audit Committee vouches to the full Board that the proposed financial statements should be disclosed.
- 54. In addition to responsibility for reviewing policy on earnings press releases and other guidance provided to analysts and rating agencies, the Audit Committee (or its Chair) is responsible for reviewing all earnings press releases.
- 55. All of these responsibilities are driven by the market-moving importance of accurate financial disclosure and the sensitivity of market actors to such information. Pfizer is a widely held stock, a bellwether in its industry, followed by dozens of analysts. On a recent day, its market capitalization was approximately \$154 *billion*, putting it within the top twenty US companies by market capitalization. Its fourth quarter earnings announcement coupled with plans to distribute cash to shareholders through a stock buyback produced an approximately 6 percent stock price increase, a valuation change of more than \$9 billion. ⁹
- 56. It is readily apparent why the Audit Committee would focus on financial reporting. Among other things, the liability risks for Pfizer and potentially the directors for inaccurate disclosure are substantial. Audit Committee members will face significant reputational loss if financial disclosure proves to be erroneous or misleading.
- 57. In the list of sixteen Audit Committee responsibilities, only one pertains to compliance, a generalized statement that the Audit Committee shall review "the status of compliance with laws, regulation, and internal procedures" and "the scope and status of systems designed to promote Company compliance with laws, regulation, and internal procedures."
- 58. The financial reporting focus of the Audit Committee is underscored by the Audit Committee Charter provision that requires the Audit Committee to "establish and oversee procedures for the confidential and anonymous receipt, retention, and treatment of complaints regarding the Company's accounting, internal controls, and auditing matters." There is no specific attention drawn to the need for Board creation and oversight of a comparable protected information channel for compliance related problems.

⁹ These figures are from Yahoo Finance, visited February 1, 2010.

- 59. Against this background, it seems clear that a company like Pfizer needs a separate committee, the Regulatory Committee, to address a discrete set of critical oversight and monitoring issues. This is because the pharmaceuticals business is heavily regulated for safety-related reasons, and because a significant share of the Company's sales is covered by Government payment or reimbursement under various programs. Violations of marketing and other safety-related regulations could result in debarment of Pfizer from continued eligibility for Government payments. This would be a financial catastrophe for the Company and its shareholders.
- 60. Pfizer's need for a Regulatory Committee is analogous to the need for a separate Risk Management Committee in financial firms. In such firms understanding the nature of the financial risks within the firm and in the financial environment is critical to the Board's monitoring of managerial performance. The Audit Committee is fully-engaged in its financial oversight role, so the Board needs to create a specially-tasked committee to focus on this critical component of the financial firm's well-being. Indeed, the recent Dodd-Frank financial reform act mandated the establishment of a risk committee for large financial firms. ¹⁰
- 61. A Regulatory Committee for Pfizer (and for other firms in heavily- regulated industries) is thus a firm-specific development designed to make the Board function more effectively in its monitoring role. ¹¹ Such a committee is an important step in the evolution of board-dominated governance, which seems to be the distinctive US approach to the governance of large publicly traded firms.

Interaction of Regulatory Committee and Audit Committee under the Corporate Integrity Agreement

62. As part of the resolution of the U.S. Government's enforcement action, in 2009 Pfizer entered into a "Corporate Integrity Agreement" that makes the Audit Committee responsible for the review and oversight of matters related to compliance with federal health care

 $^{^{10}}$ See Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 § 165(h) (requiring large financial firms to establish a Risk Committee of the Board, the membership of which must include at least one risk management expert with experience in "identifying, assessing and managing risk exposures of large, complex firms").

the Top *Compliance Week* (Sept. 26, 2004) ("Utilize a special compliance committee Far too often, companies resort to the time-tested practice of heaping additional responsibilities on their already fully-taxed audit committees. This is, as a general proposition, unwise, as it will diminish the audit committee's effectiveness in responding to the chores and obligations it already has."); Leo E. Strine, One Fundamental Corporate Governance Question We Face: Can Corporations Be Managed for the Long Term Unless Their Powerful Electorates Also Act and Think Long Term? 66 Bus. Lawyer 1, 24-26 (2010) (Vice Chancellor of Delaware Chancery Court arguing that boards should create committees, such as a compliance committee, "vital to corporate health and to the protection of society," while giving shareholders greater governance power on questions of board membership and executive compensation). See also, Declaration of Harvey Pitt, this Litigation ¶ 26(Dec. 2, 2010) (stating "there are real benefits to creating a separate board committee with primary responsibility for legal and regulatory oversight. This is especially true where a corporation, like Pfizer, operates in a highly regulated industry."); Richard C. Breeden, Affidavit in Support of Proposed Settlement, this Litigation ¶¶ 8-18 (Dec. 2, 2010) (detailing benefits of splitting off compliance monitoring function from Audit Committee into a new Regulatory Committee).

program requirements, FDA requirements and review and oversight of Pfizer's internal compliance program (the "2009 CIA") and requires an Audit Committee certification. 12

- 63. The history of the Litigation demonstrates why a Board committee is necessary to bring the appropriate level of compliance scrutiny to Pfizer's marketing activities. The 2009 CIA is the third in a series of CIA's. The first, in 2002, relied on internal compliance approach previously adopted by Pfizer and required its continuation, including the continued employment of a Compliance Officer and the maintenance of a Compliance Committee comprised of senior managers with specific compliance responsibilities under the CIA. The second, in 2004, continued this internal compliance approach. Each of these Corporate Integrity Agreements failed to avoid recurrences of serious compliance issues that led to the criminal pleas and unprecedented fines that settled the Government's enforcement actions.
- 64. The Proposed Settlement builds on the 2009 CIA by enlisting the capabilities of the Regulatory Committee to inform the Audit Committee on the adequacy of various elements of the compliance function and to protect the reporting chains of compliance information against retaliation. The Proposed Settlement also contemplates that the two Committees, acting through their respective chairs, will coordinate their activities. The Regulatory Committee under the Proposed Settlement obviously has a broader mandate than the Audit Committee under the CIA. Among other things, the Regulatory Committee needs to vet several streams of "raw" compliance information and has independent obligations and powers to trigger audits. The two Committees' activities are likely to be complements, toward the goal of minimizing the risk of significant persistent compliance problems at Pfizer.

Reform II: Ombudsman Program

- 65. The second Governance Reform is an Ombudsman Program, an alternative channel for employees to express and have addressed work-related concerns, including concerns related to Pfizer's drug marketing programs. (Id., ¶ III.) An ombudsman has become a recognized element of a high quality compliance regime. Although the Pfizer Ombudsman Program is to be managed by the Chief Compliance Officer, the Ombudsman will work out of a stand-alone office and will report directly to the "Compliance Group," a council of senior Pfizer managers. The Ombudsman will also have direct reporting rights to the Regulatory Committee.
- 66. The capacity of the board or a committee to monitor is dependent on the quality of the information that it receives. Rank-and-file employees may be important sources of information, but they may feel disempowered or be concerned about exposure and retaliation

¹² Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and Pfizer ¶ III.3 (2009).

¹³ See, e.g., Charles Howard, Promoting an Ethical Culture: The Organizational Ombudsman, COMPLIANCE AND ETHICS PROFESSIONAL (August 2010); Am. Bar Ass'n, The Organizational Ombudsman: Origins, Roles, and Operations – A Legal Guide (2010).

should they report on wrong-doing.¹⁴ An Ombudsman Program can mitigate such anxieties by providing a protected channel for employees to express work-related concerns, including concerns about the kind of wrongful conduct that produced the Government's enforcement actions. Thus an Ombudsman will be a position to watch for a pattern of compliance-related concerns that can be reflected to the Compliance Group or directly to the Regulatory Committee.

67. The effectiveness of an Ombudsman Program in this regard depends upon the Ombudsman's self-perception of independence and the relevant audience's perception of that independence. The Corporate Governance Reforms add force on both dimensions. A reporting relationship with a designated Board committee and with a senior management group should enhance the Ombudsman's sense of independence and also signal to Pfizer's internal constituency that the Ombudsman office is a credible recipient of information about corporate misconduct.

Reform III: Compensation Review

- 68. The Regulatory Committee, in conjunction with the Compensation Committee, is charged with consulting with management over the appropriate design of compensation practices for Pfizer sales and marketing employees and for speakers and advisory board members, who may also be involved in the promotion of Pfizer products. (Id., ¶ IV.)
- 69. Commissions and other sales-related incentives are commonly part of the compensation package of sales and marketing employees. Speakers and advisory board members may be recruited because of their willingness to tout the benefits of Pfizer drugs. In both cases compensation terms may be in tension with regulatory and compliance imperatives.
- 70. The Proposed Settlement calls for a specific "evaluation" of Pfizer's practices in these two domains. The evaluation will initially be undertaken by management after consulting with the two relevant Board Committees as to the scope and depth of the evaluation. The two Committees will coordinate among themselves over how to handle the evaluation review.
- 71. As with other areas of its responsibility, the Regulatory Committee will have authority and dedicated resources to retain independent counsel and experts as it deems necessary in connection with any analysis of compensation issues.
- 72. This Reform addresses one of the chronic issues in a firm like Pfizer: the boundary between legal and illegal product promotion may be effaced by a poorly designed compensation system that fails to protect or blurs that boundary.
- 73. Marketing activities are carried out by sales and marketing personnel, who often are compensated with incentive-based tools bonuses, for example. One lesson of the financial crisis is that poorly-structured compensation incentives can produce perverse results for the firm.

¹⁴ See, e.g., Aaron S. Kesselheim, David M Studdert, & Michelle M. Mello, Whistle-blowers' Experiences in Fraud Litigation against Pharmaceutical Companies. 362(19) *N Engl J Med 1832* (2010).

As a result, boards of financial firms, in particular compensation committees, will be given new responsibilities in reviewing and monitoring compensation schemes within firms, not just the compensation of senior officers.

74. Applying a comparable "lesson learned" to Pfizer, the Reforms include Board-level review of compensation schemes for sales and marketing personnel to assure the alignment of incentives with compliance objectives. Such Board review will also include the compensation of speakers and advisory board members, who are not fulltime Pfizer employees. This Board review will be addressed through collaboration between the Compensation Committee, which has general responsibility for compensation oversight within the firm, and the Regulatory and Compliance Committee, with its focus on compliance.

Reform IV: Compensation Clawback

- 75. Incentives are designed to affect behavior ex ante. But incentives may have perverse effects or may be incomplete. Thus an ex post mechanism like compensation clawback may be necessary to assure that employees do not retain the fruits of wrongful conduct and also to heighten the overall pro-compliance incentive effects of a compensation scheme. The Reforms include a procedure by which the Regulatory Committee initiates a Board decision to claw back incentive-based compensation from a manager who engaged in significant wrongful conduct in the regulatory or compliance area or who supervised an employee who engaged in such behavior. (Id., ¶ V.)
- 76. The Reforms detail the circumstances that trigger a Committee response: criminal or civil charges by the government that lead to conviction or a civil settlement, a *qui tam* action in which the government intervenes, and any other government or regulatory action that the Board decides has caused "significant regulatory, financial, or reputation damage to the Company." (Id.) In such a case the Regulatory Committee must make a written recommendation to the Compensation Committee with respect to the clawback of incentive based compensation.
- 77. This mandate will require familiarity with the facts and invites a deeper digging into the circumstances. Thus, not only will the threat of a clawback serve the interests of deterrence, but the Committee's particular fact-finding responsibility will add to the other information flows coming to the Regulatory and Compliance Committee about compliance issues in the firm.
- 78. The two step procedure, entailing involvement of the Compensation Committee as well as the Regulatory and Compliance Committee, will give responsibility and ownership to two differently-tasked Board committees. This will further underline within the Board as a whole the importance of oversight of drug marketing regulatory compliance.

Value of the Reforms to Pfizer

- 79. In my opinion, the Reforms embodied in the Proposed Settlement will significantly strengthen Board oversight of Pfizer's compliance with the FDA's drug marketing regime and other regulatory mandates and will also lead to more effective internal compliance and accountability mechanisms. In particular, the Regulatory Committee will significantly augment the Board's capacity to oversee Pfizer's compliance process and the Board's capacity to act effectively should a problem appear. The result will be to reduce significantly the possibility of recurrent wrong-doing as reflected in the 2002, 2004, and 2009 settlements of Government complaints. Because of the financial and franchise risks to the Company from further violations of the FDA regulatory regime, these Reforms will thus provide significant value for Pfizer and its shareholders.
- 80. Pfizer faces particular risks from further violations because it seems to be regarded by Justice Department officials as a somewhat cynical actor as well as a recidivist. As stated by the Acting U.S. attorney who played a significant role in negotiating the Government plea, "The size and seriousness of this resolution, including the huge criminal fine of \$1.3 billion, reflect the seriousness and scope of Pfizer's crimes. Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated." ¹⁵
- 81. Given this history, in the event of a future significant violation, Pfizer faces financial exposure from criminal and civil fines that presumably would be considerably greater than the \$2.3 billion resolution costs of the prior investigation. The nightmare scenario, however, is that the Government would debar Pfizer from eligibility for receipt of payments from government programs such as Medicare and Medicaid. A recent analysis indicates that more than 40 percent of national health care expenditures are covered by U.S. Government funds, especially Medicare, Medicaid, and programs of the Department of Veterans Affairs. Taking a conservative approach, it would appear that at least 30 percent of Pfizer revenues would be lost by a federal debarment. Assuming that margins are constant across drug classes, this would further mean an immediate drop in profits of 30 percent, producing a 30 percent drop in market capitalization, a \$46 billion value loss.
- 82. These are admittedly rough calculations but the conclusion is not: a strong federal sanction would be enormously costly to Pfizer and its shareholders. Because the Reforms that would be put in place by the Proposed Settlement will, in my opinion, significantly reduce the likelihood of recurrent serious compliance and other regulatory violations, they have

¹⁶ Earl Dirk Hoffman, Jr. et al, Brief Summaries of Medicare and Medicaid, Actuary Office, Centers for Medicare & Medicaid Services, Dep't. HHS (as Nov. 1, 2008) (percent estimates computed from dollar amounts provided).

¹⁵ U.S. Dep't of Justice, District of Massachusetts, Press Release, Justice Department Announces Largest Health Care Fraud Settlement in Its History, Sept. 2, 2009.

substantial financial benefit for Pfizer and its shareholders. At the very least, they mitigate the risk of a very bad downside outcome.

- 83. In an important sense, quantification of the Reforms' benefits in terms of Pfizer's earnings and market capitalization is to take too narrow a frame. Our system of corporate governance is set up on the assumption that management's charge is to maximize subject to legal and regulatory constraints. That sustains the legitimacy of a particular firm as well as the system as a whole. The Reforms significantly increase the likelihood that Pfizer will operate within these constraints and thus on that ground alone the Proposed Settlement delivers substantial value.
- 84. Appreciating the value to Pfizer of the Reforms also becomes a way of appreciating that the Proposed Settlement may well be superior to a litigated outcome with a significant monetary recovery. I believe that no jury could return a verdict that required creation of a Regulatory Committee or adoption of the other Reforms. Such Reforms emerged only in settlement negotiations. The fact that the Proposed Settlement came only on the eve of a summary judgment submission, after an unsuccessful motion to dismiss and extensive discovery, rather than early in litigation, suggests the reluctance of the Pfizer Board to make these changes. In other words, it is this Litigation, rather than the shock of the criminal plea and \$2.3 billion fine, that has produced these Reforms.

Public Benefit of the Reforms

85. As attested by two former SEC Chairs, Messrs. Breeden and Pitt, there will be significant public benefit from Pfizer's creation of a Regulatory Committee as an instructive example for firms that operate in a highly-regulated environment. The governance of such firms would be improved by such a Committee, which would bring focused Board-level attention to critical risk and control issues. Pfizer would be the largest firm in the Fortune 100 to have such a committee. As a top 20 firm (by market capitalization), a constituent of the Dow-Jones stock

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¹⁷ A Shearman & Sterling survey of corporate governance at the Fortune 100 suggests that Pfizer would be the only firm with a Regulatory Committee. Shearman & Sterling, Corporate Governance of the Largest US Public Companies 41 (2010) (no equivalent committees identified among "additional committees of the board"). Mr. Breeden's independent examination of the proxy statements of other drug companies indicates that one other Fortune 100 firm has an equivalent committee, Eli Lilly, and another, Abbott Laboratories, has a near-equivalent. Amgen, a smaller firm, also has an equivalent committee. He finds that none of the committee charters at those firms "describes the committee's responsibilities with the level of breadth, details and focus that is reflected in the proposed scope of responsibility of Pfizer's Regulatory Committee." Affidavit in Support of Proposed Settlement of Richard C. Breeden, supra, at ¶ 17.

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market index, and firm that has sought to foster the perception of leadership in corporate governance, Pfizer's example would be a powerful one. The question for boards, for shareholder governance activists, and for proxy advisors, may well become: Why doesn't this particular firm also have a Regulatory Committee?

Conclusion

86. Based on the above, it is therefore my opinion that the Corporate Governance Reforms reflected in the Proposed Settlement will create significant value for Pfizer and its shareholders by reducing the risk of recurrent wrong-doing in the regulatory and compliance area. I also believe that the Corporate Governance Reforms will generally serve as an important model of corporate governance reform for firms that operate in compliance-intensive environments.

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